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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/623,268

08/30/2000

Frank Filser

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EXAMINER

LAZORCIK, JASON L

ART UNIT

PAPER NUMBER

1791

MAIL DATE

DELIVERY MODE

07/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/623,268	FILSER ET AL.	
	Examiner	Art Unit	
	JASON L. LAZORCIK	1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-34 and 41-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-34 and 41-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on November 15, 2007 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16-34 and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlwend (US 6,106,747) in view of Applicant's Exhibit A: the John Halloran letter dated 6 April 2004 (supplied to the PTO in the response of 5/3/2004).

Wohlwend teaches (Column 1, lines 55-65) a method for forming dental prostheses having precise dimensions. In general, the reference teaches that a form for the prosthetic is "profiled" from a prepared block of material by cutting the desired shape in enlarged dimensions to "compensate for shrinkage during sintering". This enlarged form is subsequently sintered to the density and hardness required for the end use application.

The specific process disclosed by Wohlwend (Column 3, lines 24-42 and Column 4, lines 51-54) includes the steps of:

1. Processing ceramic to form a "homogeneous" blank of ceramic material (see Column 3, lines 45-63; claim 3, and claim 5) from powdered ceramic materials
2. Scanning and digitizing the dimensions of a positive model of a skeletal structure (Column 2, Lines 34-38);
3. Enlarging the dimensions of the model by "the appropriate enlargement factor" (Column 2, lines 40-43);
4. Transferring the enlarged dimensions to a porous ceramic blank via material removal (Column 2, Lines 40-42);

5. Dense sintering the blank; and (Column 1, Lines 63-65, Claim 1, and Claim 7)
6. Facing the blank with a coating material (Column 4, lines 48-58).

Although Wohlwend does not explicitly teach “linearly” enlarging the dimensions “in all directions” as claimed, the reference does disclose applying the enlargement factor to the digitized prosthetic dimensions in order to “compensate for shrinkage during sintering”. One of ordinary skill in the art equipped with the Wohlwend teachings would either find the linear compensation an implicit component of the instant reference or would alternatively recognize said “linear” enlargement “in all directions” as a merely obvious extension over the prior art.

Wohlwend does not explicitly limit the enlargement factor to conform the formula presented in Claims 16, 32, and 33.

It is instructive here to examine the Applicants enlargement factor to understand its intuitive and obvious mathematical basis. First Applicant teaches a material density prior to sintering, ρ_r or “the relative density, and a post-sintering density, ρ_s or “the achievable relative density”. Assuming conservation of mass, the fraction ρ_s/ρ_r is simply a mathematical representation for fractional volume shrinkage for the ceramic body from the pre-sintering stage to the post-sintering stage. The cube root of the volume ratio merely reduces the volumetric contraction (ρ_s/ρ_r) into a linear vector quantity which one of ordinary skill would recognize an obvious and natural form for scaling a digital

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representation (read x,y,z coordinates) of a volumetric body. Restated, although Wohlwend does not explicitly set forth the details of Applicants claimed enlargement factor, said enlargement factor details appear on their face to merely state an obvious solution to the enlargement operation contemplated and disclosed by Wohlwend.

The Halloran letter teaches the level of ordinary skill in the art at the time of the invention with respect to ceramic shrinkage during sintering and specifically the ordinary level of skill with respect to the “enlargement factor”. To this end, Halloran explicitly states;

- a. Ceramic engineers *routinely consider the shrinkage during fabrication*...moulds, tools, CAD dims, etc. are routinely made larger by “enlargement factors”...*This is a normal part of the ceramic art, and need not be specified in detail.*
- b. Also *well known* in the art...the *enlargement factor is computed from starting density and sintered density.*
- c. *It is commonly understood* that the reproducibility of the dimensions of the finished ceramic article depends upon the starting density, so *efforts are made to control this factor as part of the ordinary practice of ceramic manufacture.*

In short, Halloran teaches that it is a merely routine operation for a skilled ceramic engineer to compute enlargement factors by taking into account the starting density (“relative density”) and final density (“achievable relative density”) of a ceramic material. Further, one having an ordinary level of skill in the art would necessarily undertake steps to “control” the precision (e.g. calculating f to 4 decimal places) of the enlargement factor as a routine quality control measure to insure “the reproducibility of the dimensions of the finished ceramic article”. Finally and most importantly, Halloran

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instructs that the calculation of "enlargement factors" are such a trivial matter and so notoriously well known in the art that they "need not be specified in detail".

Therefore, although Wohlwend may not specify the particular details of the enlargement factor as claimed by Applicant, the Halloran letter teaches that the claimed enlargement factor is a merely obvious extension over the prior art. Specifically, Halloran discloses that calculation of the enlargement factor is a "normal part of the ceramic art" and "need not be specified in detail". It follows that Applicants explicit rendering of these calculation details is insufficient to patentably distinguish the claimed invention over method disclosed in the prior art.

Similarly, the Wohlwend reference teaches a single iteration of the disclosed steps for fabricating a single tooth. Although the Wohlwend reference does not expressly require repeating all process steps for each artificial tooth substitute to be produced, such a repeated process would clearly fall within the purview of a skilled practitioner in the arts. Specifically, one of ordinary skill in the arts would be motivated to repeat all process steps including, *inter alia*, a step of calculating the enlargement factor as a routing quality control initiative. Restated, where the Wohlwend reference teaches essentially every feature of Applicants claimed process, an explicit requirement to repeat all of said steps would represent a trivial extension over the prior art for one of ordinary skill in the arts.

The Examiners position on this matter is supported by the Halloran letter which states in part that the engineers “routinely consider the shrinkage during fabrication”, and that such a factor is “Also well known in the art...(and) computed from starting density and sintered density”. Finally, Halloran indicates that controlling the enlargement factor is “part of the ordinary practice of ceramic manufacture”.

Response to Arguments

Applicant's arguments filed November 15, 2007 have been fully considered but they are not persuasive.

In view of Applicants submitted Exhibit B relating the Densply sales figures for 2006 and 2007, it appears that Applicant intention is to present evidence of commercial success for the claimed invention as an attempt to overcome the prior issued grounds of rejection. The Densply press releases dated February 06, 2007, April 30, 2007, and July 31, 2007 have all been carefully considered by the Examiner, but said documents are not deemed to constitute persuasive evidence of commercial success for the currently claimed invention. Specifically, while the Examiner does not contest that each of the noted documents exhibits net sales increases for the Densply, there is no evidence to conclude that the sales figures are directly dependent upon or correlated with the claimed invention.

On this matter, the MPEP §716.03 clearly establishes that, "To be given substantial weight in the determination of obviousness or nonobviousness, evidence of secondary considerations must be relevant to the subject matter as claimed, and therefore the examiner must determine whether there is a nexus between the merits of the claimed invention and the evidence of secondary considerations. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 305 n.42, 227 USPQ 657, 673-674 n. 42 (Fed. Cir. 1985), cert. denied, 475 U.S. 1017 (1986). The term "nexus" designates a factually and legally sufficient connection between the objective evidence of nonobviousness and the claimed invention so that the evidence is of probative value in the determination of nonobviousness. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 7 USPQ2d 1222 (Fed. Cir.), cert. denied, 488 U.S. 956 (1988).

With particular respect to secondary evidence of commercial success, MPEP§716.03 [R-2] states that "An applicant who is asserting commercial success to support its contention of nonobviousness bears the burden of proof of establishing a nexus between the claimed invention and evidence of commercial success." Further, "an applicant must show that the claimed features were responsible for the commercial success of an article if the evidence of nonobviousness is to be accorded substantial weight. See *In re Huang*, 100 F.3d 135, 140, 40 USPQ2d 1685, 1690 (Fed. Cir. 1996)". Finally, the section indicates that "Gross sales figures do not show commercial success absent evidence as to market share, *Cable Electric Products, Inc. v. Genmark, Inc.*, 770 F.2d 1015, 226 USPQ 881 (Fed. Cir. 1985), or as to the time period during which the

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product was sold, or as to what sales would normally be expected in the market, Ex parte Standish, 10 USPQ2d 1454 (Bd. Pat. App. & Inter. 1988).”

In the instant case, Applicant presents evidence showing a general rise in gross sales figures, however Applicants evidence fails to unequivocally tie these reported sales increases to the commercial success of the claimed invention. Restated, Applicant has failed to present evidence establishing a nexus between the Densply sales figures and the merits of the particularly claimed invention.

Applicants other arguments regarding calculation of an enlargement factor for each blank of ceramic material and a step of processing ceramic powder to form a ceramic blank are addressed under the new grounds of rejection presented above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON L. LAZORCIK whose telephone number is (571)272-2217. The examiner can normally be reached on Monday through Friday 8:30 am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven Griffin can be reached on (571) 272-1189. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

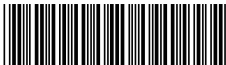
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JLL

/Richard Crispino/

Supervisory Patent Examiner, Art Unit 1791

Application Number**Application/Control No.**

09/623,268

Examiner

JASON L. LAZORCIK

**Applicant(s)/Patent under
Reexamination**

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